Exhibit 46

State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS

Exhibit to the November 25, 2009 Declaration of Philip D. Robben in Support of Defendants' Joint Motion for Partial Summary Judgment

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

Managed Pharmacy Care, et al. Plaintiff(s), vs. David Maxwell Jolly Defendant(s).	Case No. CV 09-382 CAS (MANx) ORDER GRANTING PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

I. INTRODUCTION AND BACKGROUND

On September 16, 2008, the California Legislature passed Assembly Bill 1183 ("AB 1183"), which was subsequently signed by the Governor and filed with the Secretary of State on September 30, 2008. AB 1183 amends Cal. Welf. & Inst. Code. § 14105.19 and mandates that, effective March 1, 2009, Medi-Cal reimbursement payments to some fee-for-service providers will be reduced by one percent or five percent, depending on provider type. Particularly relevant to the instant action, AB 1183 enacts a modified Cal. Welf. Inst. Code § 14105.191(b)(3) so as to require that Medi-Cal fee-for-service payments to pharmacies be reduced by 5 percent.

These reductions mandated in AB 1183 replace the ten percent rate reduction put into place by Assembly Bill X3 5 ("AB 5"), which is scheduled to terminate on February 28, 2009. See Cal. Welf. & Inst. Code § 14105.19(b)(1). AB 5 was passed by the California Legislature on February 16, 2008. On August 18, 2008, the ten percent rate reduction mandated by AB 5 was partially enjoined by this Court in a related action, Independent Living Center of Southern California, Inc. v. Sandra Shewry, CV-08-3315 CAS (MANx). In issuing the preliminary injunction, this Court found that petitioners had, *inter alia*, demonstrated a strong likelihood of success in showing that AB 5 was preempted by § 30(A) of the Medicaid Act (referred to herein as "§ 30(A)"). The Court's August 18, 2008 order is currently being appealed to the Court of Appeals for the Ninth Circuit.[1]

On January 16, 2009, Managed Pharmacy Care, Independent Living Center of Southern California, Inc., Gerald Shapiro, Sharon Steen, and Tran Pharmacy, Inc. filed the instant action against David Maxwell-Jolly, Director of the Department of Health Care Services of the State of California. Plaintiffs' complaint challenges the five percent Medi-Cal reimbursement rate reduction to providers of pharmacy services under AB 1183. Plaintiffs seek an order directing defendant "to set aside his preempted policy to implement § 14105.19 Welf. & Inst. Code, of AB 1183, and the 5% Rate Reduction, and, to refrain from implementing the same; including but not limited to refraining from reducing payments by five percent or by any other deduction, / / /

[1] The Court's August 18, 2008 order was issued on remand from the Ninth Circuit, after plaintiffs appealed this Court's original June 25, 2008 ruling on their preliminary injunction motion. The Court's June 25, 2008 order found that plaintiffs in Independent Living lacked any federal rights under § 30(A), and therefore had denied petitioners' motion for preliminary injunction. On appeal, the Ninth Circuit held that plaintiffs could bring suit under the Supremacy Clause to enjoin AB 5 as preempted under the Medicaid Act, and remanded to this Court. See Independent Living Center of Southern California et. al. v. Sandra Shewry et al., 543 F.3d 1050 (9th Cir. 2008).

to pharmacy providers in the Medi-Cal FFS program, for services furnished on and after March 1, 2009."[2] Compl. at 8; Mot. at 1.

On February 2, 2009, plaintiffs filed the instant motion for a preliminary injunction. Defendant filed an opposition thereto on February 11, 2009. A reply was filed on February 16, 2009. Plaintiffs' motion for a preliminary injunction is currently before the Court.

II. LEGAL STANDARD

A preliminary injunction is appropriate when the moving party shows either (1) a combination of probable success on the merits and the possibility of irreparable harm, or (2) the existence of serious questions going to the merits and that the balance of hardships tips sharply in the moving party's favor. See Rodeo Collection, Ltd. v. West Seventh, 812 F.2d 1215, 1217 (9th Cir. 1987). These are not two distinct tests, but rather "the opposite ends of a single 'continuum in which the required showing of harm varies inversely with the required showing of meritoriousness.'" Id. A "serious question" is one on which the movant "has a fair chance of success on the merits." Sierra On-Line, Inc. v. Phoenix Software, Inc., 739 F.2d 1415, 1421 (9th Cir. 1984).

III. DISCUSSION

A. ELEVENTH AMENDMENT AND PRUDENTIAL STANDING

Before addressing the merits of plaintiffs' argument for preliminary injunction, the Court must first address two arguments raised by defendant: (1) that plaintiffs' suit is barred by the Eleventh Amendment and (2) that plaintiffs lack standing. The Court finds that neither of these arguments is persuasive.

The essence of defendant's Eleventh Amendment argument is that plaintiffs' suit effectively amounts to a request for money damages to be paid out of the state treasury, in violation of the Eleventh Amendment. See Opp'n at 20 ("the primary purpose

[2] On January 26, 2009, plaintiff Managed Pharmacy Care was voluntarily dismissed as a plaintiff in this action.

driving this lawsuit is to obtain funds from the State above the 5% payment reduction"), citing Edelman v. Jordan, 415 U.S. 651 ("Thus the rule has evolved that a suit by private parties seeking to impose a liability which must be paid from public funds in the state treasury is barred by the Eleventh Amendment"). However, the Court disagrees with defendant's characterization of plaintiffs' claim. Plaintiffs complaint does not seek money damages, but instead seeks only prospective injunctive relief – namely, an injunction preventing defendant from enforcing a state law that, defendants argue, is preempted by the Medicaid Act. Such prospective injunctive relief against a state official is permissible under Ex Parte Young, 209 U.S. 123 (1908), even where such an injunction will have an effect on the state treasury. See, e.g., Miliken v. Bradley, 433 U.S. 267 (federal courts permitted "to enjoin state officials to conform their conduct to requirements of federal law, notwithstanding a direct and substantial impact on the state treasury").

Defendant also argues that plaintiffs lack prudential standing, because they are health care providers who have no "rights" under the federal law they seek to enforce. Opp'n at 22. The Court disagrees. In its September 17, 2008 order in the related action Independent Living, 543 F.3d at 1065, the Ninth Circuit determined that petitioners in that action had standing:

> Petitioners include independent pharmacies and health care providers participating in the State's Medi-Cal program that, according to their complaint, will be directly injured, by loss of gross income, when the ten-percent rate reduction takes effect. The Supreme Court repeatedly has recognized that such [direct economic] injuries establish the threshold requirements of Article III standing. Moreover, this injury is directly traceable to the Director's implementation of AB 5, and would certainly be redressed by a favorable decision of this court enjoining the ten-percent rate reduction.

As in Independent Living, plaintiffs in the instant action include independent pharmacies participating in the Medi-Cal program, and an independent living center which serves over 8,000 individuals with disabilities annually, 96 percent of whom are Medi-Cal beneficiaries, who, plaintiffs allege, would be directly injured by the five percent Medi-Cal reimbursement rate reduction. See Vescovo Decl. ¶ 5. Therefore, the Ninth Circuit's holding in Independent Living, 543 F.3d at 1065, with regard to standing applies in this case as well, and the Court finds defendant's argument that plaintiffs lack standing to be without merit.

B. LIKELIHOOD OF SUCCESS ON THE MERITS

Pursuant to the holding of the Ninth Circuit in the related action Independent Living, 543 F.3d at 1065, the Court finds, as an initial matter, that plaintiffs may pursue a claim for relief under the Supremacy Clause based on the allegation that AB 1183 is preempted by § 30(A). Here, plaintiffs' Supremacy Clause claim is predicated upon federal conflict preemption. Under general principles of federal preemption, state law is preempted only to the extent that it actually conflicts with federal law. Pacific Gas & Elec. Co. v. State Energy Comm'n, 461 U.S. 190, 204 (1983). Such a conflict may arise either where "compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Id. at 203-04 (citations omitted).

Thus, to prevail on the merits plaintiffs will have to prove either that it is not possible for the Department to comply with both AB 1183 and the Medicaid Act or that AB 1183 stands as an obstacle to the enforcement of § 30(A). As such, the Court turns to the statutory provisions at issue here.

The "quality of care" provision of § (30)(A) provides that

> [a] State plan for medical assistance must . . . provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary to safeguard

> against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care.

42 U.S.C. § 1396a(30)(A). The "equal access" provision of § 30(A) provides that

> [a] State plan for medical assistance must . . . provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are . . . sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

Id.

In Orthopaedic Hospital v. Kizer, 1992 WL 345652 (C.D. Cal. 1992) ("Orthopaedic I"), plaintiff-hospital providers filed suit pursuant to 42 U.S.C. § 1983 ("§ 1983"), claiming that the Director violated § 30(A) by setting reimbursement rates for hospital outpatient services without considering the effect of hospital costs on efficiency, economy, and quality of care.[3] Id. at *1. The district court concluded that § 30(A) was enforceable in a § 1983 action, and that the Department "had a judicially enforceable obligation" to consider and make findings each time it modified reimbursement rates. Id. at *2. According to the district court, § 30(A) obligated the Department to consider efficiency, economy, and quality of care, which it referred to as the "relevant factors." Id. at *4. The district court found that the Director had acted arbitrarily and capriciously in establishing six of the seven challenged rates. Id. The court then remanded the matter to the Department for further consideration. Id. at *14.

[3] The hospitals did not, however, challenge the rates under the "equal access" provision. Orthopaedic I, 1992 WL 345652 at *14 n.4.

Upon remand, the Department conducted a rate study, and readopted the reimbursement rates without change. Orthopaedic Hospital II/III, 103 F.3d at 1495.

The hospitals returned to the district court, filing two lawsuits (Orthopaedic II/III) that the district court consolidated, arguing that the adopted rates did not comply with § 30(A). Id. The district court entered judgment in favor of the Department, finding that the Department was not statutorily required to consider hospital costs when setting reimbursement rates. Id. The hospitals appealed, and the Ninth Circuit reversed. The Ninth Circuit's interpretation held that § 30(A) "provides that payments for services must be consistent with efficiency, economy, and quality of care, and that those *payments* must be sufficient to enlist enough providers to provide access to Medicaid recipients." Id. at 1496 (emphasis in original). The Ninth Circuit therefore concluded that under § 30(A)

> the Director must set hospital outpatient reimbursement rates that bear a reasonable relationship to efficient and economical hospitals' costs of providing quality services, unless the Department shows some justification for rates that substantially deviate from such costs. To do this, the Department must rely on responsible cost studies, its own or others', that provide reliable data as a basis for its rate setting.

Id.[4] Further, the Ninth Circuit found that "[i]t is not justifiable for the Department to

[4] See e.g., Alaska Dep't of Health & Soc. Servs. v. Ctrs. for Medicare & Medicaid Servs., 424 F.3d 931, 940-41 (9th Cir. 2005); see also Arkansas Med. Soc'y v. Reynolds, 6 F.3d 519, 530 (8th Cir. 1993) ("We agree with the trial court's conclusion that the relevant factors that DHS is obliged to consider in its rate-making decisions are the factors outlined in 42 U.S.C. § 1396a(a)(30)(A)."); cf. Methodist Hosps. v. Sullivan, 91 F.3d 1026, 1030 (7th Cir. 1996) (finding that § 30(A) does not require a state to consider any particular factors, but rather, requires that the state arrive at substantive results consistent with the Medicaid Act); Rite Aid, Inc. v. Houstoun, 171 F.3d 842 (3d Cir. 1999) (same).

reimburse providers substantially less than their costs for purely budgetary reasons." Id. at 1499 n.3.[5]

Whatever else its effect may have been, it is clear that Sanchez v. Johnson, 416 F.3d 1051 (9th Cir. 2005) left undisturbed the rule announced in Orthopaedic II/III that § 30(A) creates duties on behalf of the Department, i.e., the duty to consider efficiency, economy, and quality of care when establishing reimbursement rates. Indeed, the Sanchez court recognized that "[§ 30(A)] speaks . . . of the *State's obligation* to develop 'methods and procedures' for providing services generally."[6] Sanchez, 416 F.3d at

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[5] Subsequently, in Sanchez v. Johnson, 416 F.3d 1051 (9th Cir. 2005), the Ninth Circuit held that § 30(A) does not confer individual rights that are enforceable under 42 U.S.C. § 1983. Id. at 1060. However, in Independent Living, 543 F.3d 1050 (9th Cir. 2008), the Ninth Circuit held that "a plaintiff seeking injunctive relief under the Supremacy Clause on the basis of federal preemption need not assert a federally created 'right,' in the sense that term has been recently used in suits brought under § 1983, but need only satisfy traditional standing requirements." Independent Living, 543 F.3d 1050, 1058 (9th Cir. 2008).

[6] Defendant nevertheless argues herein that under Sanchez v. Johnson, 416 F.3d 1051, plaintiffs are precluded from obtaining a judicial remedy, and that "Plaintiffs are attempting to have this Court undercut decades of federal jurisprudence to say that, merely by claiming to be suing under the Supremacy Clause instead of § 1983, a party can obtain a remedy in federal court against a state agency for non-compliance with a provision of the Medicaid Act . . . " Opp'n at 18. Defendant argues that the Ninth Circuit's holding in Independent Living, 543 F.3d 1050, does not contradict this argument, because the issue presented herein is substantially different from the issue presented in that case. Opp'n at 16 ("the only issue in front of the Court of Appeals in the Independent Living Center matter was 'whether ILC may maintain a valid cause of action to enjoin implementation of AB 5 on the basis of federal preemption"). However, the Court finds defendant's arguments unpersuasive. The Court disagrees that the issue presented herein is substantially different from the issue before the Ninth Circuit in Independent Living, 543 F.3d at 1063, and further notes that the Ninth Circuit in Independent Living specifically distinguished Sanchez:

> [In Sanchez] [w]e held that the quality of care and access provisions of § 30(A) do not give rise to the type of unambiguously conferred rights

(continued...)

1059 (emphasis added).

Because Orthopaedic II/III is binding authority on this Court, the Court finds that when the State of California seeks to modify reimbursement rates for health care

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[6](...continued)
required under Gonzaga. But our decision in [Sanchez] had nothing to say about a claim for injunctive relief brought under the Supremacy Clause. Indeed, even as the Supreme Court has tightened the requirements for seeking damages under § 1983, it has consistently reaffirmed the availability of injunctive relief to prevent state officials from implementing state legislation allegedly preempted by federal law.

Defendant also argues herein that Congress has evinced an intent that § (30)(a) not be judicially enforced. Opp'n at 17, n.8. Specifically, defendant notes that the so-called "Boren Amendment," which required that states provide the Secretary with assurances that Medicaid reimbursements according to rates that were "reasonable and adequate" to meet costs, was repealed by Congress subsequent to a Supreme Court decision finding that providers had rights under the Boren Amendment to challenge the adequacy of a state's reimbursement rates under the Medicaid statute. Opp'n at 5. However, defendant's arguments are belied by Orthopaedic II/III, which held that the Department's obligations under §30(a) were independent of the obligations imposed by the Boren Amendment:

> The Boren Amendment requires the Department to make assurances to the Secretary of Health and Human Services that rates are reasonable and adequate to meet the hospitals' costs, and requires periodic cost reports from hospitals subject to audit by the Department. These requirements are not part of § 1396a(a)(30)(A). The requirements of § 1396a(a)(30)(A) are more flexible than the Boren Amendment, but not so flexible as to allow the Department to ignore the costs of providing services. For payment rates to be consistent with efficiency, economy, quality of care and access, they must bear a reasonable relationship to provider costs, unless there is some justification for rates that do not substantially reimburse providers their costs.

Orthopaedic II/III, 103 F.3d at 1499.

services provided under the Medi-Cal program, it must consider efficiency, economy, and quality of care, as well as the effect of providers' costs on those relevant statutory factors.

In the instant motion for preliminary injunction, plaintiffs argue that AB 1183's five percent reimbursement rate reduction to pharmacies is preempted by § 30(A), because the Legislature did not consider any of the relevant factors as required by Orthopaedic II/III. To demonstrate that the Legislature did not consider any of the relevant factors, plaintiffs first note that Sec. 76 of AB 1183 indicates that the purpose of the bill was budgetary:

> [t]his act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are: In order to make the necessary statutory changes to implement the Budget Act of 2008 at the earliest possible time, it is necessary that this act take effect immediately.

Plaintiffs further describe the legislative history of AB 1183, which, they argue, demonstrates that the Legislature did not consider any of the relevant factors:

> AB 1183 was introduced Feb. 2, 2008 as a hazardous material bill and was amended several times as solely a hazardous material bill. However, on September 15, 2008, the bill was amended in the Senate so as to be at once turned into a trailer bill, on many different subjects . . . All without any public hearings or any hearing by any committee of the Legislature; was passed shortly before midnight of the same day of September 15, 2008 by the Senate; was sent to the Assembly, and was immediately passed by the Assembly before 2:08 a.m. of September 16, 2008, – all within the space of a few hours. . .

Mot. at 8.

Defendant does not appear to contest that the Legislature did not in fact consider the relevant factors prior to passing AB 1183. However, defendant appears to argue that the requirements of Orthopaedic II/III are nevertheless satisfied, because the Department itself performed a detailed analysis of the relevant factors. Opp'n at 11. Specifically, defendant submits the Department's report "Analysis of Pharmacy Reimbursement under AB 1183," ("Department Analysis") completed in February 2009, well after the enactment of AB 1183 on September 16, 2008. Opp'n at 11. The Department Analysis analyzes the impact of the five percent rate reduction, and ultimately concludes:

> After a 5% payment reduction is implemented on March 1, 2009, Medi-Cal reimbursement paid to pharmacies will comply with title 42, United States Code, section 1396(a)(30)(A). The available data indicates that Medi-Cal recipients will continue to have sufficient access to pharmacy services as required by federal law. Reimbursement will be below applicable federal upper payment limits. The 5% payment reduction will result in more efficient and economical Medi-Cal coverage. It will not have any negative impact for Medi-Cal recipients. Finally, the Department determined that Medi-Cal reimbursement will in the aggregate compensate pharmacy drug costs at a level that is well above the "range of reasonableness" that was acceptable under the repealed Boren Amendment. Thus, reimbursement will be sufficient under the more flexible requirements of section 1396(a)(30)(A).

Def's Ex. A-A (Analysis of Assembly Bill 1183 Medi-Cal Reimbursement for Pharmacies) at 12-13. The Department Analysis further concludes that the Legislature "had other alternatives for reducing spending in the Medi-Cal program, which would have had a much more negative impact on Medi-Cal recipients. Def's Ex. A-A (Analysis of Assembly Bill 1183 Medi-Cal Reimbursement for Pharmacies) at 4.

Plaintiffs, however, argue that the Department's post-hoc analysis does not satisfy the requirements of Orthopaedic II/III. The Court agrees. First, the Court notes that AB 1183, as passed by the Legislature, does not provide the Department with any discretion to determine whether the five percent rate reduction should be implemented based on the Department's consideration of the relevant factors. See Mot. at 5-6; Cal. Welf. & Inst. Code. § 14105.191 ("Notwithstanding any other provision of law, or order to implement changes in the level of funding for health care services, the *director shall reduce* provider payments, as specified in this section . . .") (emphasis added). In Orthopaedic II/III, in which rates set by the Department, rather than the Legislature, were at issue, the court stated that the "the Department must rely on responsible cost studies, its own or others', that provide reliable data *as a basis* for its rate setting." 103 F.3d at 1496 (emphasis added); see also id. at 1499-1500 ("Since the Department did not adequately consider hospitals' costs *when readopting its rates*, the Department's actions were arbitrary and capricious and contrary to law") (emphasis added). The Orthopaedic II/III holding therefore indicates that the body responsible for rate setting must consider the relevant factors contemporaneously with the adoption of the rates. Here, the legislative history shows no indication that the Legislature considered any of the relevant factors before implementing AB 1183. Instead, it appears that the Legislature enacted the rate reduction purely for budgetary reasons. Because the Department has no authority to alter the rate reduction imposed by the Legislature, the Department's post hoc analysis does not satisfy the requirements of Orthopaedic II/III.

Therefore, because the Legislature did not consider any of the relevant factors prior to implementing the five percent rate reduction in AB 1183, the Court finds that plaintiffs have a strong likelihood of success on the merits.

C. IRREPARABLE HARM

The next question before this Court is whether plaintiffs have shown that Medi-Cal beneficiaries will be irreparably harmed if the five percent rate reduction to pharmacies is permitted to go into effect. After reviewing the declarations submitted by

plaintiffs and defendant, the Court finds that plaintiffs have made a sufficient showing of irreparable harm to warrant an injunction.

Plaintiffs submit the declaration of Richard Wilson, a Certified Public Accountant who has examined various data regarding Medi-Cal prescription drug reimbursement – including the Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the State of California, a December 2007 study prepared by Myers and Stauffer, CPA's ("Myers Stauffer study") – in order to examine the impact of the five percent rate reduction on pharmacies.

Wilson notes that there are two primary cost components in the provision of prescription drugs: dispensing cost and drug acquisition cost. Wilson states that the average cost to a pharmacy for dispensing a prescription is currently $11.49 per prescription, and that the five percent reimbursement rate reduction will reduce Medi-Cal coverage for pharmacies' dispensing fees, from an average of $7.25 per prescription to an average of $6.88 per prescription. Wilson Decl. ¶ 21-22. Wilson states that the five percent reduction will therefore increase the loss incurred by pharmacies on dispensing fees from $3.56 per Medi-Cal prescription to $4.61 per Medi-Cal prescription. Wilson Decl. ¶ 22.

Furthermore, Wilson, states that the five percent rate reduction will also cause pharmacies to experience a loss on the acquisition of many brand and generic drugs. For example, Wilson states that the average acquisition costs for brand drugs is 79 percent of average wholesale price, while the amount of reimbursement that pharmacies will receive under the five percent rate reduction is only 78.85 percent of average wholesale price. Wilson Decl. ¶ 24. As a result, Wilson states that the five percent rate reduction will cause pharmacies to operate at a loss in the acquisition of 51 percent of the 200 top-selling brand drugs, and that pharmacies will make only a very small gross profit on an additional 12.5 percent of the top-selling brand drugs, a profit which will generally be insufficient to compensate for the loss that the pharmacies incur in dispensing costs. Wilson Decl. ¶ 25. With regard to generic drugs, Wilson states that

the five percent rate reduction will cause pharmacies to operate at a loss or obtain only a very small gross profit on 39 percent of the top-selling generic drugs. Wilson Decl. ¶ 31.

Wilson concludes that because pharmacies, on average, will suffer a financial loss to acquire and dispense brand drugs as a result of the five percent rate reduction, many will be forced to stop dispensing many if not most brand products to Medi-Cal patients. Wilson Decl. ¶ 28. Wilson further concludes that, as a result of the five percent rate reduction, many pharmacies will also be forced to stop dispensing many of the generic drugs to Medi-Cal patients. Wilson Decl. ¶ 32.

Petitioners also submit additional declarations providing further evidence to the effect that the five percent rate reduction will cause independent pharmacy owners to limit the scope of the services they provide to Medi-Cal beneficiaries. Specifically, plaintiffs submit the declarations of ten independent pharmacists, many of whom state that the five percent rate reduction will significantly affect their ability to provide services to Medi-Cal patients. See Davis Decl. ¶ 8; Dunckel Decl. ¶ 8; Faast Decl. ¶ 8. For example, the pharmacists' declarations state that the total reimbursement under AB 1183 will cover neither their acquisition costs nor their dispensing costs on many drugs, and that, as a result, they will not be able to fill all Medi-Cal prescriptions, including some prescriptions for AIDS medications and name-brand antipsychotropics, and will not be able to serve all existing Medi-Cal customers. See Davis Decl. ¶ 8, 11; Dunckel Decl. ¶ 8, 11; Faast Decl. ¶ 11; Shapiro Decl. ¶ 26; Tran Decl. ¶ 17; Medina Decl. ¶ 11; Tran Decl. ¶ 20. Some of the pharmacists also state that the five percent rate reduction will prevent them from accepting new Medi-Cal patients. See Dunckel Decl. ¶ 11; Jeha Decl. ¶ 11. In addition, some pharmacists say they will be forced to cut the business hours of the pharmacy and lay off employees in order to remain profitable, while others state that the five percent rate reduction will force them out of business. See, e.g., Jeha Decl. ¶ 11; Leonelli Decl. ¶ 11. Some pharmacists state that the five percent rate reduction will prevent them from providing prescription delivery service to their Medi-

Cal beneficiary patients who are unable to leave their homes. See Medina Decl. ¶ 9; Shapiro Decl. ¶ 26.

Defendant counters that plaintiffs' showing of harm is speculative and that, in fact, under the five percent rate reduction, "an extremely high percentage of pharmacy costs will be compensated and the more efficient pharmacies should be able to obtain a substantial profit from providing services under the Medi-Cal program." Opp'n at 5. For example, defendant notes that the Department Analysis estimates that under the five percent rate reduction, pharmacies will continue, on average, to be compensated above their costs for Medi-Cal prescriptions. See Def's Ex. A-A at 8 (stating that the five percent rate reduction will reduce the aggregate Medi-Cal reimbursement for prescription drugs from compensating approximately 108.7 percent of pharmacy costs to approximately 103 percent of pharmacy costs).

Defendant also submits the declaration of Kevin Gorospe, who is employed as the Department's Chief of Medi-Cal Pharmacy Policy Branch. Gorospe states that he has examined plaintiffs' submitted declarations, and has calculated that, with one exception, the total revenue loss after the five percent rate reduction for each pharmacist submitting a declaration in support of plaintiffs' motion will be less than 2 percent. Gorospe Decl. ¶ 12. Gorospe further argues that some of plaintiffs' cost estimates are misleading, because much of the average dispensing fee costs are costs of operation that a pharmacy incurs regardless of whether it provides drugs to Medi-Cal recipients, so that "continued participation in Medi-Cal by these pharmacies brings in additional reimbursement that will help to pay for many of the costs of operating a pharmacy that the pharmacy would incur even if [it] didn't participate in Medi-Cal." Gorospe Decl. ¶ 13. Gorospe further echoes the Department Analysis, stating that dispensing cost increases will not cause irreparable harm, because "Medi-Cal reimbursement for the drug itself frequently is well above pharmacy acquisition cost, that any loss on the dispensing fee portion of reimbursement is made up for by a significant profit on MediCal reimbursement for the drug itself." Gorospe Decl. ¶ 21.

The Court concludes that defendant has failed to refute plaintiffs' showing of irreparable harm. Even if defendant is correct that, on average, pharmacies will be compensated above their acquisition costs even after the five percent rate reduction, defendant has not refuted plaintiffs' findings that many brand and generic drugs will be reimbursed at a level below cost, thereby preventing pharmacies from providing those drugs and limiting access for Medi-Cal patients. Indeed, the Gorospe declaration confirms that only 98-99 percent, on average, of pharmacy costs for single source drugs will be compensated after the five percent rate reduction. Because many single source drugs are protected from competition by patents, there are no available generic alternatives. See August 18, 2008 Preliminary Injunction Order. There can be little or no doubt that Medi-Cal patients will be harmed if these necessary drugs are placed outside of their reach.

Furthermore, if pharmacists are forced to curtail services or go out of business, there is no indication that all existing customers will have access to other pharmacies in which to obtain their medication and, in some cases, home-delivery services for such medication. Indeed, the many declarations submitted by petitioners show that independent pharmacy providers, who constitute approximately thirty-three percent of the licensed community pharmacies in California, will be hard-hit by the five percent rate reduction, and may discontinue, or at least severely reduce, services to Medi-Cal beneficiaries. See August 18, 2008 Preliminary Injunction Order. Therefore, the Court concludes that plaintiffs have demonstrates a significant likelihood of irreparable harm.

D. BALANCE OF HARDSHIPS

The Court is mindful of the difficulty facing the State of California in light of its fiscal crisis.[7] However, the State has accepted federal funds under the Medicaid Act. In

[7] The Court notes that there is evidence to suggest that if the five percent rate reduction is given effect, many Medi-Cal beneficiaries will turn to more costly forms of medical care, such as emergency room care, thereby diminishing the State's projected (continued...)

so doing, the State agreed to abide by the conditions imposed by Congress. Further, retroactive relief for Medi-Cal beneficiaries will likely be inadequate and, and it will come too late, to remedy their pain, suffering, and harm to their mental and physical well-being. See e.g., Lopez v. Heckler, 713 F.2d 1432, 1437 (9th Cir. 1983). In light of the significant threat to the health of Medi-Cal recipients, reducing payments to health-care service providers will likely cause, and given that nothing in this Court's order prevents respondent from imposing a rate reduction after she has appropriately considered and applied the relevant factors, the Court finds that the balance of hardships tips in favor of granting the preliminary injunction.

E. PUBLIC INTEREST

"The district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief." Hybritech, 849 F.2d at 1458. Clearly, there is a public interest in ensuring that the State has enough money to meet its financial obligations in the face of competing demands. However, there is also a public interest in ensuring access to health care. In light of all the circumstances, including the fact that the State may decide to implement a rate change upon making a properly reasoned and supported analysis, the Court finds that the public interest does not weigh against the issuance of a preliminary injunction.

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS plaintiffs' motion for preliminary injunction. The Court hereby orders respondent Director, his agents, servants, employees, attorneys, successors, and all those working in concert with him to refrain from enforcing Cal. Welf. & Inst. Code § 14105.191(b)(3), as modified by AB 1183 beginning on March 1, 2009, by refraining from reducing by five percent payments to pharmacies for prescription drugs (including prescription drugs and traditional over-the-

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[7](...continued)
savings. See e.g., Rodde v. Bonta, 357 F.3d 988, 999 (9th Cir. 2004).

counter drugs provided by prescription) provided under the Medi-Cal fee-for-service program.[8]

Dated: February 27, 2009

CHRISTINA A. SNYDER
UNITED STATES DISTRICT JUDGE

[8] Plaintiff's motion appears to seek an injunction as to the five percent rate reduction for all pharmacy products, not just drugs. However, plaintiffs' arguments regarding irreparable harm focus on brand and generic drugs dispensed by pharmacies; plaintiffs have not shown irreparable harm as to the effect of the five percent rate reduction on other pharmacy products. Therefore, the Court limits the scope of the injunction to drug products dispensed by pharmacies.